UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,427	04/15/2005	Toshiyuki Miyata	0020-5363PUS1	2681

2292 7590 10/10/2007

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
KIM, ALEXANDER D	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
10/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/531,427	MIYATA ET AL.	
	Examiner	Art Unit	
	Alexander D. Kim	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *15-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/15/2005,11/16/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Application Status

1. By virtue of a preliminary amendment filed on 04/15/2005, claim 19 has been canceled; and claims 1-18 have been amended.

Thus, claims 1-18 are pending in this instant case.

Election

2. Applicant's election with traverse of Group I, (Claims 1-14 and 17-18) in the reply filed on 07/27/2007 is acknowledged. The traversal is on the ground(s) that the Examiner must examine the entire application if the search and examination of an entire application can be made without a serious burden. Applicants allege searching one group the Examiner is necessarily searching the other group since the claims are so closely related in subject matter. However, the argument above does not corresponds to the lack of unity. As noted in the previous office action, this is not found persuasive because each Group lacks the unity of invention because the technical feature of Group I does not constitute an advance over prior art by Remuzzi et al. (2002, Blood, vol. 100, pages 778-785). Thus, technical feature of Group I is not special and the restriction is proper in accordance with a single general inventive concept under PCT Rule 13.1 and 37 CFR 1.499. Furthermore, the search of the ADAMTS-13 substrate polypeptide in Group I does not automatically search for the method for measuring ADAMTS-13 activity. The search for each Group also requires different key words because divergent subject matters on application. Searching altogether would create serious search

burden on the examination. The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-19 are pending in the instant application. Claims 15-16 are withdrawn from consideration as non-elected inventions. Claims 1-14 and 17-18 will be examined herein.

Priority

3. The instant application is a 371 filing of the International Application No. PCT/JP02/10816 filed on 10/18/2002. The Examiner notes that the requirements of national stage entry of the instant application had been completed (note assigned U.S. filing date) within 30 months of the earliest claimed priority date; the related international application includes a preliminary examination report.

Applicant's claim no foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

4. Information disclosure statements (IDSs) filed on 04/15/2005 and 11/16/2006 have been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Compliance with Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. ə

1.821(a)(1) and (a)(2). However, this application fails to fully comply with the requirements of 37 C.F.R. 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

The statement that the content of the paper and CRF copies are the same is missing.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Objections to the Specification

The specification is objected to because of the following informalities:

(a) The specification is objected to because the title is not descriptive of the claims. A new title is required that is clearly indicative of the invention to which the claims are drawn (see M.P.E.P. § 606.01). The examiner suggests the following new

title, for example: ---Substrates polypeptide for von Willebrand factor cleaving protease ADAMTS-13---

(b) The specification recites "Try^{1605}-Met^{1606}" on page 3, line 14. It should be --- Tyr^{1605}-Met^{1606}--- (emphasis added). Appropriate correction is required.

(c) The "Brief Description of the Drawings" on page 9 discloses many amino acid sequences fused with GST without appropriate point of reference (i.e., appropriate SEQ ID NO). Appropriate correction is required.

(d) The specification (from page 30, line 25 to page 31, line 1; page 31, lines 9-10; page 31, lines 5-11, lines 16-17 and line 24; page 32 line 10; and pages 34-35) recites many amino acid sequences fused to GST without appropriate SEQ ID NO. Appropriate correction is required.

Claim Objections

6. Claims 1-5 are objected to because of the following informalities:

The use of abbreviation "ADAMTS-13" or "VWF" should be spelled out on a first appearance in claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

~~The following is a quotation of the second paragraph of 35 U.S.C. 112:~~

~~The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.~~

AK, 9/28/07

~~Claims 2 and 3 are rejected under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.~~

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-14 and 17-18 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-6 are drawn to a substrate polypeptide for ADAMTS-13, which comprises an amino acid sequence which begins at one of amino acids 764 to 1605 and ends at one of amino acids 1606 to 2813 of the amino acid sequence of wild-type human VWF depicted in SEQ ID NO: 1 in the Sequence Listing, wherein the polypeptide beginning at amino acid 764 and ending at amino acid 2813 of SEQ ID NO: 1 of the Sequence listing is excluded. Claims 7 (Claims 8-14 dependent therefrom) are

drawn to a polypeptide of Claims 1-6 wherein an amino acid sequence has homology of at least 50%. Claim 10 is drawn to a polypeptide of Claims 1-6 wherein an amino acid sequence has one or more of deletion, insertion, substitution, or addition (or combination thereof) in the amino acid sequence. Claims 17 and 18 are drawn to a diagnostic composition and a kit (respectively) for *in vitro* test having the polypeptide of Claim 7.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (paraphrased from *Enzo Biochemical Inc. v. Gen-Probe Inc.* (CAFC (2002) 63 USPQ2d 1609).

University of Rochester v. G.D. Searle & Co. (69 USPQ2d 1886 (2004)) specifically points to the applicability of both *Lily* and *Enzo Biochemical* to methods of

using products, wherein said products lack adequate written description. While in *University of Rochester v. G.D. Searle & Co.* the methods were held to lack written description because not a single example of the product used in the claimed methods was described, the same analysis applies wherein the product, used in the claimed methods, must have adequate written description as noted from *Enzo Biochemical* (see above).

The instant specification teach a substrate polypeptide for ADAMTS-13 protease comprises an amino acid sequence including the cleavage site (i.e., the peptide bond between Y1605 and M1606) comprising a certain fragment of SEQ ID NO: 1. However, the breadth of claim includes any polypeptide as long as the polypeptide includes a sequence beginning at anywhere between 764-1605 and ending at anywhere between 1606 to 2813. For example, the smallest polypeptide encompasses a di-peptide having Tyr-Met sequence (because Tyr and Met corresponds to residues 1605 and 1606, respectively, in the SEQ ID NO: 1), and there are no limits to a sequence that can be added onto said di-peptide, which is still encompassed by the polypeptide of Claim 1 except the polypeptide of 764-2813 of SEQ ID NO: 1. The breadth of Claim 7 encompasses any polypeptide as long as it contains Tyr or Met because of the limitation having homology of at least 50% or higher from the claimed polypeptide described above for Claim 1. The breadth of Claim 10 encompasses any polypeptide because of the limitation of deletion, insertion, substitution, or addition (or combinations thereof) from the polypeptide described above for Claim 1. The prior art teaches a human VWF as disclosed in Girma et al. (1986, Blood, vol. 67, pages 1356-1366). However, the

prior art and the instant specification do not describe any polypeptide or any variant thereof sufficiently to represent the correlation between the structure and function of claimed genus that is a substrate polypeptide for ADAMTS-13 protease. Thus, the instant specification and the prior art cannot describe the structure of a very broad claimed genus and one skilled in the art would not be in possession of the claimed genus by the instant specification.

8. Claims 1-14 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for a substrate polypeptide for a human ADAMTS-13 comprising the amino acid sequence D1596-R1668 of SEQ ID NO: 1, does not reasonably provide enablement for a substrate polypeptide for ADAMTS-13 comprising any polypeptide comprising Tyr-Met or any variation(s) thereof.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many

factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The nature of the invention is drawn to a substrate polypeptide for ADAMTS-13 protease comprises an amino acid sequence including the cleavage site (i.e., the peptide bond between Y1605 and M1606) comprising a certain fragment of SEQ ID NO: 1. However, the breadth of claim includes any polypeptide as long as the polypeptide includes a sequence beginning at anywhere between 764-1605 and ending at anywhere between 1606 to 2813. For example, the smallest polypeptide encompasses a di-peptide having Tyr-Met sequence (because Tyr and Met corresponds to residues 1605 and 1606, respectively, in the SEQ ID NO: 1), and there are no limits to a sequence that can be added onto said deceptive, which is still encompassed by the polypeptide of Claim 1 except the polypeptide of 764-2813 of SEQ ID NO: 1. The breadth of Claim 7 encompasses any polypeptide as long as it contains Tyr or Met because of the limitation having homology of at least 50% or higher from the claimed polypeptide described above for Claim 1. The breadth of Claim 10 encompasses any polypeptide because of the limitation of deletion, insertion, substitution, or addition (or combinations thereof) from the polypeptide described above for Claim 1. The instant specification and prior

art disclose a few example of substrate polypeptide (see Girma et al. and the instant examples). However, applicants disclose no direction or guidance on how to make and use any other substrates for ADAMTS-13 respective to the very widely varying and a very broad breadth of claimed polypeptide. Thus, the specification and prior art fail to describe how to make and use the claimed genus sufficiently. Furthermore, the substrate polypeptide require a certain amino acid sequence of SEQ ID NO: 1, i.e. D1596 to R1668 as evidenced by the Kokame et al. (E. publication of 2003 Sep 25, Blood, vol. 103, pages 607-612). Therefore, it is unpredictable for any polypeptide encompassed by the instant claims to be a substrate polypeptide for any ADAMTS-13 from any source. Thus, it is unpredictable for any polypeptide, as described above in the breadth of claims, encompassed by the claims for one skilled in the art to make and use the full scope of claimed polypeptide. The said unpredictability makes the relative skill required in the art very high. For all of the above reason, it would require undue experimentation necessary for any claimed substrate polypeptide for any ADAMTS-13.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-10 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Claims 1-10, as written, does not sufficiently distinguish over a polypeptide as they naturally exist (or a naturally occurring mutant

polyepeptide) because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206, USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g. by insertion of "isolated" or "purified" as taught by the specification. See M.P.E.P. § 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-14 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Girma et al. (1986, Blood, vol. 67, pages 1356-1366).

Claims 1-6 are drawn to a substrate polypeptide for ADAMTS-13, which comprises an amino acid sequence which begins at one of amino acids 764 to 1605 and ends at one of amino acids 1606 to 2813 of the amino acid sequence of wild-type human VWF depicted in SEQ ID NO: 1 in the Sequence Listing, wherein the polypeptide beginning at amino acid 764 and ending at amino acid 2813 of SEQ ID NO: 1 of the Sequence listing is excluded. Claims 7 (Claims 8-14 dependent therefrom) are

drawn to a polypeptide of Claims 1-6 wherein an amino acid sequence has homology of at least 50%. Claim 10 is drawn to a polypeptide of Claims 1-6 wherein an amino acid sequence has one or more of deletion, insertion, substitution, or addition (or combination thereof) in the amino acid sequence. Claims 17 and 18 are drawn to a diagnostic composition and a kit (respectively) for *in vitro* test having the polypeptide of Claim 7.

Girma et al. teach a purified human von Willebrand factor (VWF) (see bottom of right column, page 1356). Thus, Girma et al. has identical amino acid sequence to the instant SEQ ID NO: 1. Because Claims 2-6 and 8-9 are also drawn to a polypeptide comprising an amino acid sequence as described in Claim 1 or 7 with additional limitations, the VWF of Girma et al. meets the limitations of Claim 1-9 and 11-14. A polypeptide described by the recitation of "one or more amino acid deletion, insertion, substitution, or addition (or combination thereof)" in Claim 10 also encompass the naturally occurring VWF of Girma et al. since a certain combination of insertion and deletion results in a polypeptide having unmodified amino acid sequence. The VWF of Girma et al. have a polypeptide having the sequence of 1 to 763 at the N-terminal which is encompassed by the scope of limitation "a tag sequence at the N-terminal"; thus, meeting the limitations of Claims 11-12. There is a Cys35, which can be used to attach to a meleimide plate; thus meeting the limitation of Claim 13. The purified VWF of Girma et al. was loaded on to the SDS-PAGE gel for electrophoresis and the protein VWF inside the SDS-PAGE gel meets the limitation of Claim 14 reciting "immobilized on a solid phase". The purified VWF by Girma et al. was precipitated with ammonium

sulfate and divided into aliquots to be used for digestion later, wherein the precipitated VWF meets the limitation of a Claim 17 (i.e., a diagnostic composition comprising mutant substrate polypeptide according to Claim 7), and the aliquoted VWF meets the limitation of Claim 18 (i.e., a kit comprising mutant substrate polypeptide according to Claim 7). Thus, the VWF of Girma et al. meets the limitation of Claims 1-14 and 17-18.

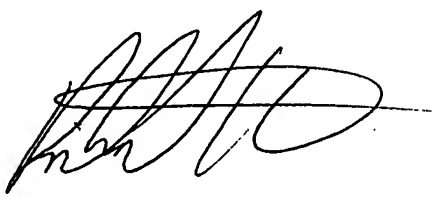
Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alexander Kim
September 17, 2007



RICHARD HUTSON, P.
PRIMARY EXAMINER

Notice to Comply	Application No.	Applicant(s)	
	10/531,427	MIYATA ET AL.	
	Examiner	Art Unit	
	Alexander D. Kim	1656	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: The statement that the content of the paper and CRF copies are the same is missing.

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510 or (571) 272-2533
For CRF Submission Help, call (571) 272-2510 or (571) 272-2533
PatentIn Software Program Support
Technical Assistance..... (571) 272-2510 or (571) 272-2533
To Obtain PatentIn Software.....www.uspto.gov/web/patents/software.htm

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY